LEAVING MEDICARE BENEFICIARIES IN LIMBO

Medicare Uses Coverage with Evidence Development to Limit Access: By the Numbers

- **27** NCDS with CED issued since the program’s start in 2005
- **11.5** Years: Average time from CED start until Medicare retired the CED*
- **22** Currently active NCDS with CED
- **13.5** Years of longest ongoing CED with clinical trials
- **33** Largest number of clinical trials reported for an active CED
- **13** Years of longest ongoing CED with registries
- **4** NCDS with CED evidence collection retired*
- **1** NCD with CED for FDA-approved therapies denying coverage for their medically appropriate, clinically approved use (Alzheimer’s disease).

*Once a CED requirement is deemed completed by Medicare, Medicare will cover the product without requiring participation in a clinical study.

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Coverage with Evidence Development (CED) Limits Patient Access:

Medicare may deny coverage of FDA-approved treatments or services through a National Coverage Determination requiring CED, which limits Medicare coverage only to beneficiaries participating in an approved clinical research study.

No one has coverage unless and until the clinical research study is open, is enrolling patients, and the patient meets the necessary eligibility requirements for the study and is enrolled.

CED Delays Coverage and Restricts Access:

CED’s stated purpose is to collect additional data Medicare will use to re-assess coverage in the future. But the CED process has taken 11.5 years on average before retiring evidence collection – during that time beneficiaries have limited access and no clear time frame for when the coverage limitations will be revisited.

CEDs Adversely Impacts Underserved Populations and Exacerbates Health Disparities:

CED clinical study requirements favor large, urban medical centers and often leave out rural populations without access. These CED clinical trials and registries have historically had a poor record of enrolling diverse participants.

MEDICARE BENEFICIARIES SHOULDN’T HAVE TO WAIT TO ACCESS FDA-APPROVED TREATMENTS. CED REQUIREMENTS ARE NOT THE ANSWER.

Learn more at www.fightchronicdisease.org.